K111219

JUN 30 2011

Section 8: 510(k) Summary

The following information is provided as required by 21 CFR § 807.92 for Generic Medical Device's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

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Date of Submission: May 2, 2011

Proprietary Name: GMD Universal Urinary Incontinence Sling™-1011

Common Name: Mesh, Surgical, Polymeric

Regulatory Class: Class II

Product Codes: OTN

Predicate Device(s): GMD Universal Sling (K083471)
GMD Universal Sling™-1012 (K101440)

Device Description:

The GMD Universal Urinary Incontinence Sling™-1011 is a sterile, single use device for the treatment of female Stress Urinary Incontinence. The Universal Urinary Incontinence Sling™-1011 is comprised of the same polypropylene knitted mesh as its Model 1010 and Model 1012 predicates, protected by the same disposable polypropylene sheath as its Model 1012 predicate with a disposable low density polypropylene universal sleeve at each end made of the same material and similar in design to the sleeve of its Model 1010 predicate, for attachment of the sling to GMD's reusable trocars (sold separately). Similar to both predicates, the Universal Urinary Incontinence Sling™-1011 is used for inside-out / bottom-up and outside-in / top-down approaches. Similar to both predicates, the method of placement and surgical approach chosen by the physician should be appropriate for the patient's diagnosis and anatomy.

Intended Use:

The GMD Universal Urinary Incontinence Sling-1011 is a suburethral sling indicated for use in women for treatment of stress urinary incontinence (SUI) resulting from either urethral hypermobility and/or intrinsic sphincter deficiency. The mesh is placed transvaginally using reusable introducers (sold separately) either through a transobturator or retropubic approach.

The use of the device in males and children under 18 years of age is not supported by clinical studies.

Modifications Made to the Model 1010 in the Model 1011

The following table describes the changes in the Model 1010 Universal Sling that are found in the Model 1011.

Product Feature	Model 1010	Model 1011	Reason
Sheath Design	470mm wide, 300m long roll of extruded LDPE supplied by extrusion supplier to sling manufacturer who cuts stamps and heat seals that material into ~16mm wide right and left sheaths	Right A 15.5mm sheath wide LDPE extrusion is cut to specified lengths by extrusion supplier and supplied to sling manufacturer for assembly into slings.	Improved ease of sheath removal during sling tensioning
Sheath Design	LDPE Sheath thickness 7 microns	LDPE Sheath thickness increased to 16.9 microns	Improved ease of removal
Sheath Design	Two centrally overlapping sheaths with one of the sheaths tapered and inserted into the other sheath, which has a constant width from end to end.	Both sheaths have a constant width from end to end. One sheath is slightly narrower than the other sheath, which allows the overlapping insertion.	Improved ease of removal
Bonding Area Design	The current assembly process attaches the sheath/mesh subassembly using heat shrink tube and mechanically squeezing the mesh and sheath into the barbs of the LDPE sleeve. The sheath in this process is wrapped around the barbed end of the sleeve. The shrink tube is left on the mesh/sheath/sleeve assembly to provide mechanical grip.	Manufacture by a standard catheter re-flow process in which the mesh and sheath materials are welded to a smooth sleeve end and the shrink tube is removed after being used as a manufacturing tool. The sleeve is the same LDPE material as the 1010 sleeve (Same resin used for 1010, 1011 sleeves and 1012 bullet tip).	Provides a smoother bonding area and reduces the force required to pull the bonding area through tissue. Addresses user input obtained through the post market surveillance process.
Sleeve Design	Molded LDPE sleeve in sailor blue. Proximal trocar insertion	Molded LDPE sleeve in USP Class VI Blue Colorant. Proximal trocar insertion	No material change. Colorant specified as USP standard. Trocar insertion point relocated to reduce resistance during

Product Feature	Model 1010	Model 1011	Reason
	point on the sleeve is 8 mm from the proximal end.	point is at the proximal end of the sleeve	sling assembly positioning.

Comparison to Predicate Devices:

The GMD Universal Urinary Incontinence Sling™-1011 has the same intended use and similar technological characteristics as the predicate devices: GMD Universal Sling™-1010 (K083471) and GMD Universal Sling™-1012 (K101440). The GMD Universal Urinary Incontinence Sling™-1011 is equivalent to the predicates.

Non-Clinical Studies:

Bench and animal studies were performed on the GMD Universal Sling and previously submitted with the premarket notification cleared under K083471. Additional bench testing was performed on the modifications to the Model 1010 predicate incorporated into the Model 1011 sling. Cadaver labs were conducted on the Model 1010 predicate and submitted with K083471, on the Model 1012 predicate and submitted with K101440 and were conducted on the Model 1011 to prove the substantial equivalence of the Model 1011 to its predicates. The data demonstrates that the GMD Universal Urinary Incontinence Sling™-1011 is substantially equivalent to the predicate device(s) and that there is no change in the safety and effectiveness due to the modification.

Conclusion:

The GMD Universal Urinary Incontinence Sling™-1011 has a similar design and the same intended use as the predicates GMD Universal Sling ™-Model 1010 (K083471) and GMD Universal Sling™-1012 (K101440). Biocompatibility testing and the current knowledge of the material provided by scientific literature demonstrated the appropriateness of the device materials for the proposed intended use. Bench and cadaver lab testing demonstrates that the GMD Universal Urinary Incontinence Sling™-1011 has similar mechanical and performance characteristics as the predicate devices as described in Section 13. Therefore, the GMD Universal Urinary Incontinence Sling™-1011 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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SEP 28 2012

Re: K111219
Trade/Device Name: GMD Universal Urinary Incontinence SlingTM-101 1
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: May 2, 2010
Received: May 4, 2011

Dear Mr. Morgan:

This letter corrects our substantially equivalent letter of June 30, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 6: Indications for Use Statement

510(k) Number: K111219

Device Name: GMD Universal Urinary Incontinence Sling™-1011

Indications for Use:

The GMD Universal Urinary Incontinence Sling-1011 is a suburethral sling indicated for use in women for treatment of stress urinary incontinence (SUI) resulting from either urethral hypermobility and/or intrinsic sphincter deficiency. The mesh is placed transvaginally using reusable introducers (sold separately) either through a transobturator or retropubic approach.

The use of the device in males and children under 18 years of age is not supported by clinical studies.

Prescription Use ☒ AND/OR Over-The-Counter Use ☐

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111219